REMARKS/ARGUMENTS

The Office Action mailed March 23, 2007 has been received and reviewed. Claims 1 through 113 are currently pending in the application. Claims 4, 5, 29, 30, 52, 53, 72 through 79, 82, 83, and 106 through 113 have been withdrawn in response to a restriction/election of species requirement. Claims 1 through 71 and 80 through 105 stand rejected. Applicants have amended claims 1, 26, 49, 80, 104, and 105, and respectfully request reconsideration of the application as amended herein.

Information Disclosure Statement(s)

The Examiner did not consider the foreign patents and non-patent literature cited in the Information Disclosure Statement and PTO/SB/08 filed on September 27, 2004 because copies of the cited documents were not provided. Submitted herewith is a duplicate copy of the Information Disclosure Statement and PTO/SB/08, along with copies of the cited foreign patents and non-patent literature. Applicants respectfully request that the foreign patents and non-patent literature cited in the Supplemental Information Disclosure Statement of September 27, 2004 be considered and made of record in the above-referenced application, and that an initialed copy of the Form PTO/SB/08A that accompanied that Supplemental Information Disclosure Statement be returned to the undersigned attorney as evidence of such consideration.

Double Patenting Rejection Based on U.S. Patent Application No. 10/985,116 (Publication No. 2005/0281879)

Claims 1 through 71 and 80 through 105 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent Application 10/985,116 (Publication No. 2005/0281879). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

Double Patenting Rejection Based on U.S. Patent Application No. 10/985,122 (Publication No. 2005/0106214)

Claims 1 through 71 and 80 through 105 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent Application No. 10/985,122 (Publication No. 2005/0106214). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

Double Patenting Rejection Based on U.S. Patent Application No. 10/295,814 (Publication No. 2004/0024069)

Claims 1 through 71 and 80 through 105 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57, 115, and 116 of U.S. Patent Application No. 10/295,814 (Publication No. 2004/0024069). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

Double Patenting Rejection Based on U.S. Patent Application No. 10/628,984 (Publication No. 2004/0022859)

Claims 1 through 71 and 80 through 105 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-55 of U.S. Patent Application No. 10/628,984 (Publication No. 2004/0022859). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as

acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

Double Patenting Rejection Based on U.S. Patent Application No. 10/606,969 (Publication No. 2004/0001889)

Claims 1 through 71 and 80 through 105 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent Application No. 10/606,969 (Publication No. 2004/0001889). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

Double Patenting Rejection Based on U.S. Patent Application No. 10/295,603 (Publication No. 2003/0180364)

Claims 1 through 71 and 80 through 105 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1through 21, 23 through 52, 54 through 87, and 110 through 112 of U.S. Patent Application No. 10/295,603 (Publication No. 2004/0180364). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

Double Patenting Rejection Based on U.S. Patent Application No. 10/295,527 (Publication No. 2003/0170289)

Claims 1 through 71 and 80 through 105 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6 through

48, and 98 through 104 of U.S. Patent Application No. 10/295,527 (Publication No. 2003/0170289). In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

35 U.S.C. § 102(b) Anticipation Rejections

Anticipation Rejection Based on International Patent Publication No. WO 02/38185 to Dunn et al.

Claims 1 through 3, 6 through 9, 14 through 19, 21 through 28, 31 through 34, 39 through 44, 46 through 51, 54 through 57, 62 through 67, 69 through 71, 80, 81, 84 through 87, 92 through 97, and 99 through 105 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dunn et al. (International Patent Publication No. WO 02/38185). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The 35 U.S.C. § 102(b) anticipation rejections of claims 1 through 3, 6 through 9, 14 through 19, 21 through 28, 31 through 34, 39 through 44, 46 through 51, 54 through 57, 62 through 67, 69 through 71, 80, 81, 84 through 87, 92 through 97, and 99 through 106 are improper because each and every element of the claims is not found in the cited reference.

Independent claims 1, 26, 49, 80, 104, and 105 have been amended to require that the polymer be a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer.

Dunn et al. discloses a controlled release implant composition including a thermoplastic polyester that is insoluble in aqueous medium or body fluid, an organic solvent, and an

antihyperalgesic opiate. Dunn et al. does not disclose, teach or suggest compositions that reduce initial burst index nor does it disclose compositions that achieve that result by modifying the comonomer ratio of the blend of polymers to reduce the burst index and regulate duration of delivery. More specifically, Dunn et al. does not disclose a polymer that comprises a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer.

Applicants respectfully request withdrawal of the present rejection in view of the amendments and arguments herein.

Anticipation Rejection Based on U.S. Patent No. 6,130,200 to Brodbeck et al.

Claims 1 through 3, 6 through 28, 31 through 51, 54 through 71, 80, 81, and 84 through 105 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Brodbeck et al. (U.S. Patent No. 6,130,200). Applicants respectfully traverse this rejection, as hereinafter set forth.

The 35 U.S.C. § 102(b) anticipation rejections of claims 1 through 3, 6 through 28, 31 through 51, 54 through 71, 80, 81, and 84 through 105 are improper because each and every element of the claims is not found in the cited reference.

As previously discussed, independent claims 1, 26, 49, 80, 104, and 105 have been amended to require that the polymer be a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer.

Brodbeck et al. discloses an injectable depot gel composition containing a polymer, a solvent (having a miscibility in water of 7 wt % or less) selected from lower alkyl ester and arylalkyl ester of benzoic acid that can dissolve the polymer to form a viscous gel, a beneficial agent, and an emulsifying agent if the form of a dispersed droplet phase in the viscous gel. Although Brodbeck et al. recognizes the problem of high initial burst index release of beneficial agents, it does not disclose, teach or suggest compositions that achieve reduction in initial burst index by modifying the comonomer ratio of the blend of polymers to reduce the burst index and regulate duration of delivery. Instead, this reference solves the problem by incorporating an emulsifying agent into the single polymer composition. More specifically, Brodbeck et al. does not disclose a polymer that comprises a blend of polymers including at least one lactic acid-based

polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer.

Applicants respectfully request withdrawal of the present rejection in view of the amendments and arguments herein.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on International Patent Publication No. WO 02/38185 to Dunn et al.

Claims 10-13, 15, 20, 35 through 38, 40, 45, 58 through 61, 63, 68, 88 through 91, 93, and 98 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dunn et al. (International Patent Publication WO 02/38158). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The 35 U.S.C. § 103(a) obviousness rejections of claims 10-13, 15, 20, 35-38, 40, 45, 58-61, 63, 68, 88-91, 93, and 98 are improper because Dunn et al. does not teach or suggest all the claim limitations.

As previously discussed, independent claims 1, 26, 49, and 80 have been amended to require that the polymer be a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer. Also, as previously discussed, Dunn et al. does not teach or suggest compositions that reduce initial burst index nor does it teach or suggest compositions that achieve that result by modifying the comonomer ratio of the blend of polymers to reduce the burst index and regulate

duration of delivery. More specifically, Dunn et al. does not teach or suggest a polymer that comprises a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer.

The nonobviousness of independent claim 22 precludes a rejection of claim 31 which depends therefrom because a dependent claim is obvious only if the independent claim from which it depends is obvious. *See* In re Fine, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988), *see also* MPEP § 2143.03. Therefore, the Applicant requests that the Examiner withdraw the 35 U.S.C. § 103(a) obviousness rejection to independent claim 22 and claim 31 which depends therefrom.

Applicants respectfully request withdrawal of the present rejection in view of the amendments and arguments herein.

ENTRY OF AMENDMENTS

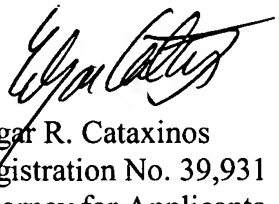
The amendments to claims 1, 26, 49, 80, 104, and 105 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application.

CONCLUSION

Claims 1-3, 6-28, 31-51, 54-71, 80, 81, and 84-105 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine

that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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